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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/997,209	11/28/2001	William D. Huse	P-IX 5066	3759

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EXAMINER

WESSENDORF, TERESA D

ART UNIT PAPER NUMBER

1639

DATE MAILED: 01/28/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/997,209

Applicant(s)

HUSE, WILLIAM D.

Examiner

T. D. Wessendorf

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) 11-13 and 25-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 14-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

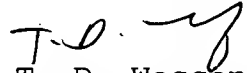
- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_. 6) ☐ Other: \_\_\_\_\_

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Wessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (703) 306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7924 for regular communications and (703) 308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

  
T. D. Wessendorf  
Primary Examiner  
Art Unit 1639

tdw  
January 23, 2004

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**DETAILED ACTION**

***Election/Restrictions***

Newly submitted claims 41-43 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the claims are drawn to a different and distinct subject matter i.e., a method of generating the cell composition.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 41-43 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

***Status of Claims***

Claims 1-43 are pending.

Claims 11-13 and 25-43 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions.

Claims 1-10 and 14-24 are under examination.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

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Claims 1-10 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

In view of the amendments to the claims this rejection has been overcome.

***Claim Rejections - 35 USC § 112, second paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 and 14-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The rejection of the claims in the last Office action is withdrawn in view of the amendments to the claims.

However, the claims as amended are rejected as follows:

1. It is not clear how each cell can be made to express only a single variant of nucleic acid with the exclusion of the other variant nucleic acids. Furthermore, it is not clear how the variant nucleic acid is located within each of the different cell at an identical site in the genome.

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***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendment Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e))

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Claims 1, 10, 14 and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by Stemmer (6,132,970) for reasons advanced in the last Office action.

***Response to Arguments***

Applicants argue that Stemmer does not disclose the composition.

In response, attention is drawn to col. 49, line 24 up to col. 53, line 12 which discloses the cell composition transfected with a vector containing variants of nucleic acid. See further Fig. 2, col. 10, lines 50-65; col. 16, lines 41-50; col. 19, lines 40-50; col. 23, lines 5-47 and etc. Accordingly, the specific cell composition of Stemmer fully meets the broad claimed non-yeast eukaryotic cell comprising nucleic acid variants.

Claims 1-6, 8, 10, 14-17, 20 and 22-24 are rejected under 35 U.S.C. 102(a) as being anticipated by Choi et al (Nucleic Acids Research) for reasons set forth in the last Office action.

***Response to Arguments***

Applicants argue that Choi, at best, appears to describe a BAC vector and expression of a BAC library but does not teach the claimed composition.

In reply, attention is directed to page iii wherein Choi describes a composition comprising of a plant cell (i.e., a non-

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yeast cell, as claimed) transfected with the vector containing the BAC library, as stated by applicants above. See further e.g., Fig. 1 and page vii. Accordingly, the specific cell composition of Choi fully meets all the claimed limitation of the broad cell composition.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-10 and 14-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stemmer in view of Biard-Piechczyk (hereinafter Biard).

Each of the Stemmer and Biard is discussed in the last Office action. Stemmer does not describe recombination using loxP-Cre system. However, Biard discloses said loxP-Cre. Biard further discloses at page 72, that the use of loxP-Cre result in selection of nucleic variants encoding Abs with higher affinities. Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was



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made to use in the system of Stemmer a loxP-Cre in the manner as taught by Biard for its advantageous effect of obtaining a product from the library with higher affinities.

The rejection of the claims under 35 USC 102 over Bouhassira et al or Treco et al or Le or Thomas or et al has been overcome in view of the amendments to the claims and applicants' arguments.

Claims 1-10 and 14-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Zarling et al (U.S. 20030105039).

Zarling discloses at [0127] -[0129] a composition e.g., insect cells Xenopus, rodent cell lines, primate cell lines or human cells transfected with vectors containing pools or libraries of variant nucleic acid sequences. Accordingly, the specific cell composition of Zarling anticipates the broad claimed cell composition.

#### **Conclusion**

Pati et al discloses sequence alterations using homologous recombination.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D.